REMARKS

Claims 1-55 stand rejected under 35 U.S.C. 112, 1st para. as failing to comply with the written description, in particular for addition of the limitation "and/or" as regards a "completely erodible and/or water-soluble" polymer coat. Insofar as it may apply to the present claims, this rejection is traversed.

The amendment of the claims was already accepted by examiner and an Office Action following the amendment included no objection or rejection of the language added by amendment. Applicants submit that the language as issued, "completely erodible or water-soluble", covers embodiments wherein the polymer coat will dissolve or erode in water. Therefore, a polymer coat that is "completely erodible and/or water-soluble" meets the limitations of the original claims since such a material will dissolve, erode, or dissolve and erode in water. A material that dissolves and erodes in water necessarily includes the individual properties of dissolution or erosion. Therefore, the term "and/or" is merely considered a cosmetic grammatical clarification of the language of the original claim. In other words, the phrases cover essentially the same subject matter. Nonetheless in order to expedite prosecution of the present claims, claims 1, 24-27, 36, 40, 50, 51, 53 and 54 have been amended to replace the term "and/or" with the term "or".

Applicants submit that this rejection has been overcome and request that it be withdrawn.

Claim 36 stands rejected under 37 C.F.R. 1.75 for double patenting and as for being a substantial duplicate of claim 1. Insofar as it may apply to the present claims, this rejection is traversed.

Claim 36 has been amended to include the subject matter of claim 37, which has been canceled. Claim 1 does not include the requirement of a second polymer in the inert polymer coat. Dependent claims 38 and 39 now also include the subject matter of claim 37; therefore, they are not a substantial duplicate of claims 21 and 23, respectively.

Applicants submit that this rejection has been overcome and request that it be withdrawn.

Claims 1-55 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 6,613,357 (the '357 Patent) and claims 1-38 of U.S. Patent No. 6,605,302 (the '302 Patent). Insofar as it may apply to the present claims, this rejection is traversed.

Applicants note the following.

The basis for this type of rejection is the potential for impermissible extension of a patentee's right to exclude with regard to a claimed invention. Double patenting may exist between an issued patent and a pending application. In this regard, "the examiner must determine whether the grant of a second patent would give rise to an unjustified extension of the rights granted in the first patent." (MPEP 804 I.A.) This type of rejection can be overcome by the filing of a terminal disclaimer in the application. A terminal disclaimer is properly required in an application rejected under this doctrine if the issuance of the claims in the application results in an extension of the rights of the conflicting patent, and the claims of the application are obvious over the claims of the conflicting patent. Applicants submit that neither of these requirements is met in the present case.

Applicants submit that an issuance of the instant claims will not result in an extension of the patent rights under either of the cited patents. For the sake of this analysis, the parent patent No. 6,004,582, which underlies the present reissue application, should be considered the "first" patent and each of the cited patents should be considered the considered the "second" patent. The instant application is a reissue application based upon the parent application serial No. 09/086,871 filed May 29, 1998, which ultimately issued as U.S. Patent No. 6,004,582 on Dec. 21, 1999. None of the subject matter pending in the present claims is new matter. In other words, the actual filing date for the subject matter of the instant reissue application is actually May 29, 1998. Any patent issuing from this reissue application would already have an expiration date prior to the expiration date of each of the cited patents. In other words, issuance of the instant claims would not result in an "an unjustified extension of the rights granted in the first patent". Accordingly, rejection of the instant claims under this doctrine is improper. Moreover, the filing of a terminal disclaimer in the instant application is improper and would actually result in an unwarranted extension of the term of the ensuing reissue patent.

Applicants submit that the instant claims are patentably distinct from the claims of the '357 Patent and the '302 Patent. Application serial No. 09/725,655 underlying the '357 Patent was filed Nov. 29, 2000. The '582 Patent was cited AND overcome during prosecution of the '655 application thereby establishing a *prima facie* case of patentability over the entire subject matter disclosed in the '582 patent as determined by the USPTO. Each of independent claims 1, 19 and 36 of the '357 Patent require a specific combination of drugs as well as specific release profiles for those drugs. The instant application does not disclose the particular combination of drugs required by the claims of the '357 Patent and more specifically does not disclose the release profiles

specified for the named drugs. As noted in the '357 Patent, the particular release profiles are key toward providing an improved clinical effect. Even though some of the instant claims might dominate the claims of the '357 Patent, they remain patentably distinct therefrom. Applicants note that improvements that provide unexpected benefits remain patentable subject matter.

Application serial No. 09/907,486 underlying the '302 Patent was filed July 17, 2001. Only independent claims 1-27 of the '302 are potentially relevant to this analysis as they disclose a multi-layered osmotic device. However, each of those claims requires oseltamivir and an H1 antagonist. The basis for patentability of the invention was established upon the combined administration of both of those drugs according to the defined release profiles to achieve an improved therapeutic treatment for viral infections. The '302 Patent requires a specific combination of drugs as well as specific release profiles for those drugs. The instant claims do not specifically mention the particular combination of drugs required by the claims of the '302 Patent and more specifically do not disclose the release profiles specified for the named drugs. As above, even though some of the instant claims might dominate the claims of the '302 Patent, they remain patentably distinct therefrom.

In view of the above, Applicants submit that these obviousness-type double patenting rejections have been overcome and request that they be withdrawn.

Claims 24-35 and 40-55 stand rejected under 35 U.S.C. 103 (a) as being unpatentable over the U.S. 4,576,604 to Guittard et al. in view of U.S. 4,200,098 to Ayer et al. Insofar as it may apply to the present claims, this rejection is traversed.

Applicants note that Examiner appears to equate the microporous lamina of Guittard with the instant inert polymer coat. Guittard discloses an osmotic device comprising a drug-containing core (A) surrounded by a semipermeable membrane (B), a microporous lamina (D), and a water soluble drug-containing lamina (E). As set forth in the specification of Guittard '604, the microporous lamina acts in concert with the semipermeable membrane "to form an integral laminated wall, that maintains its physical and chemical integrity and does not separate into lamina" during operation of the device. In other words, the device of Guittard requires a bi-layered wall to control release of drug from the device. Therefore, the microporous lamina must form an integral laminated wall with the semipermeable membrane AND the integral laminated wall must maintain its physical and chemical integrity and not separate into lamina during operation of the device.

The operation and structure of the Guittard device is different than that of the device of claims 24-35 and 40-55, which require that the inert coat be completely erodible or water soluble. Even though the instant semipermeable membrane maintains its chemical and physical integrity during operation of the device, the inert coat does not maintain its physical and chemical integrity during operation of the device. This means that, in the instant device, only a single lamina (rather than two laminas) is required to control release of drug from the device. The instant device is different than and more advantageous than the device of Guittard. Guittard would not be motivated to make the microporous lamina completely erodible or water soluble, since doing so would not result in the required bi-laminate operational construction.

The combination of Guittard and Ayer fails to provide the missing elements. Ayer requires the formation of a "distribution zone" between the semipermeable membrane and an exterior membrane. During operation, a water soluble layer disposed between the semipermeable membrane and the exterior membrane dissolves thereby forming a distribution zone in which drug and fluid are present. As with Guittard et al., two laminas are required for proper functioning. Two laminas, the semipermeable membrane and the exterior membrane, control release of drug from the device. Ayer would not be motivated to make the exterior lamina water soluble or water erodible, since doing so would result in an osmotic device that has no distribution zone, and Ayer does not contemplate such a device. As with Guittard, Ayer requires that two laminas retain their physical integrity during operation of the device. The prophetic device that would result from the combination of Guittard and Ayer would then still require two laminas in order to release drug properly from the device. Thus, the operation and structure of the prophetic device is different than and less advantageous than the instant device.

Accordingly, Applicants respectfully submit that this rejection has been overcome and request that it be withdrawn.

The previously filed oath/declaration was deemed to be defective for failing to identify the country of the priority application. Submitted herewith is a supplemental declaration indicating the country of the priority application. Applicants respectfully submit that the oath/declaration is now compliant with 37 C.F.R. 1.175.

Applicants have made a diligent effort to advance the prosecution of the application by amending the claims, presenting supporting arguments, providing this amendment which now includes the amendments in a form compliant with 37 C.F.R. 1.173, and providing a corrected

oath/declaration compliant with 37 C.F.R. 1.175.

In view of the above, applicants submit that the claims are in form for allowance. An early notice of allowance thereof is requested.

Respectfully submitted,

Date: 8/16/4

Innovar, L.L.C.
P.O. Box 250647
Plano, TX 75025-0647
Ph.: 972-747-7373
Fax: 972-747-7375

Rick Matos, Ph.D. (Customer No. 24039)
Registration No. 40,082
Agent for Applicant
Email: innovarllc@sbcglobal.net